

NRC INSPECTION MANUAL

IMNS/RGB

INSPECTION PROCEDURE 87119

MEDICAL BROAD-SCOPE PROGRAMS

PROGRAM APPLICABILITY: 2800

87119-01 INSPECTION OBJECTIVES

01.01 To determine if licensed activities are being conducted in a manner that will protect the health and safety of workers, the general public and patients.

01.02 To determine if licensed activities are being conducted in accordance with U.S. Nuclear Regulatory Commission (NRC) requirements.

87119-02 INSPECTION REQUIREMENTS

The inspector should conduct the inspection in a manner that will allow him/her to develop conclusions about licensee performance relative to the following focus areas: 1) Security and control of licensed material; 2) Shielding of licensed material; 3) Comprehensive safety measures; 4) Radiation dosimetry program; 5) Radiation instrumentation and surveys; 6) Radiation safety training and practices; and 7) Management oversight. Based on selected observations of licensed activities, discussions with licensee staff, and as appropriate, a review of selected records and procedures, the inspector should determine the adequacy of a licensee's radiation safety program relative to each of the above focus areas. If the inspector's conclusions that licensee performance is satisfactory from a general review of selected aspects of the above focus areas, the inspection effort expended in reviewing that particular focus area will be complete. If the inspector determines that the licensee did not meet the performance expectation for a given focus area, the inspector should go through a more thorough review of that aspect of the licensee's program. The increased inspection effort may include increased sampling, determination of whether the licensee's procedures are adequate, and a review of selected records maintained by the licensee documenting activities and outcomes. The above focus areas are structured as a performance expectation and address the activities or program areas most commonly associated with measures that prevent overexposures, medical events, or release, loss or unauthorized use of radioactive material.

Under no circumstances will an NRC Inspector knowingly allow an unsafe work practice or a violation which could lead to an unsafe situation to occur or continue in his/her presence in order to provide a basis for enforcement action. Unless an inspector needs to intervene to prevent an unsafe situation, direct observation of work activities should be conducted such that the inspector's presence does not interfere with patient care or a patient's privacy.

Discussion of the inspector's observations and interviews with the workers should not occur during the preparation for, or delivery of medical treatment, if possible. When practicable, the inspector should exercise discretion when interviewing licensee staff in the presence of patients so that the discussions do not interfere with licensee staff administering patient care. However, there may be cases when it is appropriate to discuss such matters at such times that would allow an inspector to ascertain the adequacy of the licensee's administration of the radiation safety program. In reviewing the licensee's performance, the inspector should cover the period from the last to current inspection. However, older issues preceding the last inspection should be reviewed, if warranted by circumstances, such as incidents, noncompliance, or high radiation exposures.

02.01 Preparation. The inspector should allow adequate time to prepare for the inspection. Preparation by the inspector should include reviewing appropriate documents related to the licensee's activities, making travel arrangements, coordinating inspection related activities with appropriate staff, notifying appropriate State agencies, and selecting necessary equipment to conduct the inspection. Also, the inspector should identify whether any significant license amendments have been issued since the last inspection, or whether the licensee has informed NRC of any major program changes since the last inspection. During the conduct of the inspection, the inspector should determine from direct observations of licensed activities and discussions with cognizant licensee representatives the impact of such changes on the licensee's radiation safety program. In addition, the inspector should review the Nuclear Materials Events Database (NMED) and any regional event logs and files to determine if the licensee had any incidents or events since the last inspection. If so, the inspector should followup on those incidents or events to ensure that the licensee took appropriate actions in response to those matters.

02.02 Entrance Briefing. When the inspector arrives at the licensee's facility, he/she will inform an available senior management representative of the purpose and scope of the inspection. The inspector should note that it is not always practical to meet with licensee management, on arrival, because of the early hours during which the inspection may be conducted. However the entrance briefing should be conducted as soon as practicable.

02.03 Walk-Through Orientation Tour. Perform a walk-through tour of the licensee's facility to make general observations of the condition of the facility and the licensed activities being performed.

02.04 Security and Control of Licensed Material. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance has controlled access to and prevent loss of licensed material so as to limit radiation exposure to workers and members of the public to values below NRC regulatory limits.

02.06 Comprehensive Safety Measures. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance has implemented comprehensive safety measures to limit other hazards from compromising the safe use and storage of licensed material.

02.07 Radiation Dosimetry Program. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and a review of selected records, that the licensee's performance has implemented a radiation dosimetry program to accurately measure and record radiation doses received by workers or members of the public as a result of licensed operations.

02.08 Radiation Instrumentation and Surveys. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee

representatives, and if necessary, a review of selected records, that the licensee's performance has implemented radiation instrumentation in sufficient number, condition, and location to accurately monitor radiation levels in areas where licensed material is used and stored.

02.09 Radiation Safety Training and Practices. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance has ensured that workers are knowledgeable of radiation uses and safety practices; skilled in radiation safety practices under normal and accident conditions; and empowered to implement the radiation safety program.

02.10 Management Oversight. The inspector should independently verify through direct observations of licensed activities, discussions with cognizant licensee representatives, and if necessary, a review of selected records, that the licensee's performance for implementing a management system is appropriate for the scope of use and is able to ensure awareness of the radiation protection program, audits for ALARA practices are performed, and assessments of past performance, present conditions and future needs are performed and that appropriate action is taken when needed.

02.11 Other Medical Uses of Byproduct Material or Radiation from Byproduct Material. Due to the advancements of medical research and development, new emerging medical technologies are always on the forefront of providing optimal medical care to patients. In accordance with NRC regulations, the licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in subparts D through H of Part 35. During discussions with cognizant licensee representatives and direct observations made during the inspection, the inspector may encounter new emerging technologies being used. If an inspector encounters such activity and uses, the inspector should contact NRC regional management as soon as practicable. If further verification of such use is needed, the region should contact NMSS for further guidance.

02.12 Independent and Confirmatory Measurements. During the conduct of the inspection, the inspector should compare and independently verify, on a sampling basis, survey results or data that are used by the licensee to show compliance with NRC regulatory requirements. Independent measurements should be conducted by the inspector to ascertain the radiological conditions of the licensee's facility. The inspector should conduct these independent measurements on all inspections under this inspection procedure, unless warranted by special circumstances. The inspector shall use radiation detection instruments that are appropriately calibrated, at a minimum, on an annual basis.

02.13 Exit Meeting. The inspector will conduct an exit meeting with available senior licensee management and RSO to discuss the preliminary inspection findings, including any apparent violations, safety-related concerns, and any unresolved items identified during the inspection. In addition, the inspector should discuss any negative Performance Evaluation Factors (PEFs) and encourage the licensee to respond to the PEFs of concern. For further guidance, the inspector should refer to IP 87101, "Performance Evaluation Factors."

02.14 Post-Inspection Actions. After an inspection, the inspector shall summarize the findings with his/her appropriate NRC supervisor. This is especially important if there are, or are expected to be, controversial issues arising from the inspection findings.

Inspectors shall also meet with regional licensing staff when any pertinent licensing issues are raised during the inspection, when inspection findings impact any licensing actions, to discuss the licensee's PEF results, or to give feedback on how the licensee has addressed recent licensing actions.

Additionally, in some instances, inspection findings will warrant communication with enforcement staff, Office of Investigations staff, State liaison staff, or Federal agencies with whom NRC has a Memoranda of Understanding (MOUs).

The inspector will ensure that inspection findings are clearly documented, and reported to the licensee as appropriate. The inspector should also follow the requirements of Inspection Manual Chapter (MC) 0620, "Inspection Documents and Records," regarding notifying the licensee that retained information is subject to public disclosure and giving the licensee the opportunity to request withholding it (see MC 0620, Section 04.06.b.).

87119-03 INSPECTION GUIDANCE

General Guidance

A determination regarding safety and compliance with NRC requirements should be based on direct observation of work activities, interviews with licensee workers, demonstrations by appropriate workers performing tasks regulated by NRC, independent measurements of radiation conditions at the licensee's facility, and where appropriate, a review of selected records. A direct examination of these licensed activities and discussions with cognizant workers should be a better indicator of the performance of a licensee's overall radiation safety program than a review of selected records alone.

Some of the requirement and guidance sections of this procedure instruct the inspector to "verify" the adequacy of certain aspects of the licensee's program. Whenever possible, verification should be accomplished through discussions, direct observations, and demonstrations by appropriate licensee personnel.

Once an inspector has conducted a review of the applicable elements of a focus area in a broad capacity (e.g., looked at the "big picture") and has not identified any safety significant concerns within that area, the inspector should conclude inspection of that focus area. The inspector should note that not all of the following elements outlined below in a particular focus area need to be reviewed by the inspector if he/she concludes from selected observations, discussions and reviews that the licensee's performance is adequate for ensuring public health and safety. However, if the inspector during a review of selected elements of one of the focus areas concludes that there may be a significant safety concern, a more detailed review may be appropriate. A more detailed review may include further observations, demonstrations, discussions and a review of selected records. In the records reviewed the inspector should look for trends in those areas of concerns, such as increasing radiation levels from area radiation and removable contamination surveys, and occupational radiation doses. Records such as surveys, receipt and transfer of licensed materials, survey instrument calibrations and training may be selectively examined until the inspector is satisfied that for those areas of concerns, the records may or may not substantiate his/her concerns. If the inspector substantiates a significant safety concern regarding a particular matter, it may be more appropriate to discuss this matter with NRC regional management. During the inspection, some records that are more closely related to health and safety (e.g., personnel occupational radiation exposure records, medical events and incident reports) may be examined in detail since a review of such records is necessary to ascertain the adequacy of the implementation the radiation safety program for that particular element of a focus area.

If the inspector finds it appropriate when an apparent violation has been identified, the inspector should gather copies from the licensee, while onsite, of all records that are needed to support the apparent violation. In general, inspectors should use caution before retaining copies of licensee documents, unless they are needed to support apparent violations, expedite the inspection (e.g., licensee materials inventories), or make the licensing file more complete. In all cases where licensee documents are retained beyond the inspection, follow

the requirements of MC 0620. Especially ensure that the licensee understands that the retained record will become publicly available, and give the licensee the opportunity to request withholding the information pursuant to the requirements of 10 CFR 2.790(b)(1).

The inspector should keep the licensee apprised of the inspection findings throughout the course of the onsite inspection and not wait until the exit meeting to inform licensee senior management.

Whenever possible the inspector should keep NRC regional management informed of significant findings (e.g., safety hazards, willful violations, and other potential escalated enforcement issues) identified during the course of the inspection. This will ensure that the inspector is following appropriate NRC guidance under such circumstances.

03.01 Preparation. Before the inspection, the inspector should do the following:

- 1) Review the licensee's previous inspection history (at a minimum review the past two inspections); the license; and the status of any allegations or incidents. Note the licensee's commitments, in response to previous violations, for follow-up during the inspection;
- 2) Review regional event/incident logs, event/incident files, the docket file, the Nuclear Materials Events Database, and ADAMS to determine whether the licensee was involved in any incidents or medical events. If NRC did receive notification of an incident or event, the inspector should review that incident or event during the onsite inspection and, if appropriate, document the licensee's follow-up in the inspection record;
- 3) Discuss the licensee's program with previous inspector(s) and/or license reviewer(s), as necessary;
- 4) Notify the appropriate State radiation control program personnel;
- 5) Review pending licensing actions, if appropriate;
- 6) Obtain a map of the area and/or directions;
- 7) Make travel arrangements and prepare an itinerary;
- 8) Select calibrated instruments and perform an appropriate source check;
- 9) Select appropriate documents (The inspector should consider taking the applicable regulations, generic communications, license, NRC forms, etc.); and
- 10) Select appropriate equipment to take (The inspector should consider the type of licensee to be inspected. The equipment may include safety glasses and safety shoes, sample vials, wipes, pocket dosimeters, etc.).

During the inspection, the inspector should review (among other areas) whether the licensee is in compliance with any license amendments issued since the last inspection or with any program changes described by the licensee since the last inspection. This will require the inspector to review documentation submitted in support of the licensing action, before the inspection. The inspection will be the NRC's first opportunity to verify whether the licensee has enacted the most recent changes to the license appropriately.

03.02 Entrance Briefing. After arriving on site, the inspector should inform an available senior management representative of the purpose and scope of the inspection to be

performed. This notification should be made as soon as practical after arriving on site. However, in certain instances (e.g., unannounced inspections) the inspector may choose to inform licensee representatives of his/her presence on site following initial observations of licensed activities currently in progress.

The purpose of the entrance briefing is to inform licensee management that an inspection is being conducted, and to indicate the tentative schedule for discussing or reviewing selected inspection items with various licensee staff personnel. However, in some instances, the inspector may only need to inform management of NRC's presence on site, and apprise management that an exit briefing will be conducted, at the end of the inspection, which will detail the inspection findings.

Also, this is often an opportune time for the inspector to identify personnel to be interviewed. If appropriate, the inspector may want to schedule certain interviews with select individuals to enhance the inspector's efficiency and give the licensee the opportunity to have the most knowledgeable individuals present to respond in the areas being inspected.

Certain inspection items involving visual observations and/or records review are better performed by the inspector unannounced; therefore, these types of items should not be discussed during the entrance briefing.

03.03 Walk-Through Orientation Tour. If appropriate, the inspector should make initial observations of licensed activities to determine that materials are being safely handled and that good health physics practices are followed. The inspector should look at areas of use, storage, and disposal to make an initial assessment of the licensee's ALARA program with regard to facility design, engineering controls, house-keeping practices, etc. The inspector should ensure that observations of certain licensed activities are appropriately documented in the inspection record, if applicable.

During the course of the inspection, the inspector should selectively visit a number of research laboratories to observe workers using all types and quantities of licensed material. This is an opportune time for the inspector to ask workers to demonstrate certain procedures or to observe activities in an effort to evaluate the effectiveness of the licensee's training program.

When applicable, discuss with the cognizant licensee's representatives, or observe, the conduct of periodic tests and drills, especially for scenarios involving fires and large releases of radioactive material.

03.04 Security and Control of Licensed Material.

- A. Adequate and Authorized Facilities. Descriptions of the facilities are generally found in the application for a license and subsequent amendments that are usually tied down to a license condition as submitted by the licensee in accordance with 10 CFR 35.13. Based on direct observations made during tours of the licensee's facility, the inspector should independently verify that access to licensed material received, used, and stored is secured from unauthorized removal, and the licensee uses processes or other engineering controls to maintain exposures as low as is reasonably achievable (ALARA).
- B. Adequate Equipment and Instrumentation.
 - 1. Through discussions with cognizant licensee representatives, direct observations of licensed activities, and if necessary, a review of selected records, the inspector should ensure that equipment and instrumentation used by the licensee is appropriate to the scope of the licensed program. The inspector should independently verify through direct observations that survey instruments have been calibrated in accordance with 10 CFR 35.61. The

inspector should have cognizant licensee staff demonstrate how the instrument works and performs. The inspector should ask the individuals what actions are taken when radiation detection equipment is non-functional. During the inspection, the inspector should independently verify that for those survey and monitoring instruments available for use have current calibrations appropriate to the types and energies of radiation to be detected.

2. If appropriate, the inspector should verify that the licensee has established and implemented procedures to identify and report safety component defects in accordance with 10 CFR 21.

- C. Receipt and Transfer of Licensed Materials. Through discussions with cognizant licensee representatives, direct observations made during tours of the licensee's facility, and if necessary, a review of selected records, the inspector should verify that the licensee has received and transferred licensed materials in accordance with NRC and applicable U.S. Department of Transportation (DOT) regulations and license conditions.

Through discussions with cognizant licensee representatives, direct observation of licensed activities, and if necessary, a review of selected records, the inspector should verify that the licensee has methods for picking up, receiving, and opening packages that address how and when packages will be picked up, radiation surveys and wipe tests of packages to be done on receipt, and procedures for opening packages (such as the location in the facility where packages are received, surveyed, and opened). From those discussions, observations and reviews, if necessary, the inspector should determine what actions are taken if surveys reveal that packages are contaminated in excess of specified limits, and/or radiation levels that are higher than expected. If packages arrive during the course of an inspection, the inspector should observe, when practical, personnel performing the package receipt surveys.

Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should review the licensee's materials accounting system. The inspector should note that sometimes, a small broad-scope facility will generally need to maintain receipt records, disposal records, and records of any transfers of material. However, a large broad-scope facility may need a sophisticated accounting system which provides accurate information on the receipt of material, its location, the quantity used and disposed of, the amount transferred to other laboratories operating under the same license, and the amount remaining after decay. From those discussions and reviews, if necessary, the inspector should determine if accounting systems consider radioactive material held for decay-in-storage, near-term disposal, or transfer to other licensees. In both types of accounting systems, the inspector should ensure that the licensee has performed routine audits of those systems to ensure the accuracy of the system.

Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should ascertain if the licensee has an adequate method of determining that transfers of licensed material are made to recipients licensed to receive them (e.g., licensee obtains a copy of the recipient's current license before the transfer).

- D. Transportation. Through discussions with cognizant licensee representatives, direct observations made during the conduct of the inspection, and if necessary, a review of selected transportation records, the inspector should verify that the licensee's hazardous material training, packages and associated documentation, vehicles (including placarding, cargo blocking, and bracing, etc.), and shipping papers are adequate and in accordance with NRC and DOT regulatory requirements for

transportation of radioactive materials. Furthermore, from those discussions and reviews, if necessary, the inspector should verify if any incidents had occurred and that they were appropriately reported to DOT and NRC.

For further inspection guidance, the inspector should refer to IP 86740, "Inspection of Transportation Activities." Inspectors should also refer closely to "Hazard Communications for Class 7 (Radioactive) Materials," the NRC field reference charts on hazard communications for transportation of radioactive materials, which contain references to the new transportation requirements, and are useful field references for determining compliance with the transportation rules on labeling, placarding, shipping papers, and package markings.

- E. Material Security and Control. Through direct observations made during tours of the licensee's facility and discussions with cognizant licensee representatives, the inspector should verify that the licensee has maintained adequate security and control of licensed material. From those observations, the inspector should note areas where radioactive materials are used and stored. From further observations and discussions, the inspector should verify that licensed material in storage, in controlled or unrestricted areas, is secured from unauthorized removal or access. Also, the inspector should verify that the storage areas are locked and have limited and controlled access. For licensed material not in storage, in controlled or unrestricted areas, the inspector should verify that such material is controlled and under constant surveillance or physically secured. Controls may include a utilization log to indicate when, in what amount, and by whom, radioactive material is taken from and returned to storage areas. In addition, the inspector should verify that access to restricted areas is limited by the licensee.
- F. Written Directives. During the onsite inspection, the inspector should observe and interview individuals as they perform applicable duties to determine that individuals are knowledgeable about the need for written directives and if the licensee's written directives, as implemented, effectively ensure that radiation from byproduct material will be administered as directed by the authorized user in accordance with 10 CFR 35.41. The review should include consideration of the licensee's implementation of a continuous improvement in the following processes: monitoring, identification, evaluation, corrective action, and preventative measures. If necessary, the inspector should review selected records of written directives to confirm that these issues are adequately addressed in accordance with 10 CFR 35.2040.
- G. Patient Release. Through discussions with cognizant licensee representatives, direct observations made during the conduct of the inspection, and if necessary, a review of selected records, the inspector should determine if a licensee is knowledgeable about patient release criteria and that a process exists to establish that a patient administered radiopharmaceuticals or permanent implants containing radioactive material is releasable from control in accordance with 10 CFR 35.75.
 - 1. The inspector should note that the patient release criteria permits licensees to release individuals from control if the TEDE to any other individual is not likely to exceed 0.5 rem. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify that the licensee has taken adequate measures to ensure that patients have been released in accordance with 10 CFR 35.75.
 - 2. Through further discussions the inspector should verify that the licensee is familiar with the requirements in 10 CFR 35.75(b) to provide instructions to released individuals if the dose to any other individual is likely to exceed 0.1 rem. The inspector should note that, in general, the licensee is required to give instructions, including written instructions, on how to maintain doses to

other individuals as low as is reasonably achievable. The inspector may determine how the licensee is demonstrating compliance with this requirement by discussing the content of the instructions with appropriate licensee staff. If concerns are identified from those discussions, the inspector may find it necessary to review the sample instructions given to patients. If the licensee is required by the rule to provide instructions to breast-feeding women, the inspector should verify through further discussions and reviews, if necessary, that the instructions include guidance on the interruption or discontinuation of breast-feeding and information on the potential consequences of failure to follow the guidance.

3. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify that if the TEDE to a breast-feeding child could exceed 0.5 rem if the breast-feeding were continued, the licensee has maintained documentation that instructions were provided in accordance with 10 CFR 35.75(d).

H. Medical Events. Through discussions with cognizant licensee representatives, the inspector should determine if the licensee is knowledgeable of and in compliance with the requirements for identification, notification, reports, and records for medical events as required by NRC regulatory requirements. If necessary, the inspector should conduct a review of selected records to independently verify those discussions with such individuals. If from those reviews a previously unidentified medical event is identified by the inspector, the inspector should: 1) remind the licensee of the need to comply with the reporting requirements described in 10 CFR 35.3045, "Report and Notification of a Medical Event;" and 2) follow the procedure for reactive inspections and the guidance provided in Management Directive 8.10, "NRC Medical Event Assessment Program." Upon identification of such an event, the inspector should notify NRC regional management as soon as possible to ensure that appropriate guidance is given and matters are reviewed before completing the inspection.

I. Posting and Labeling. During tours of the licensee's facilities, the inspector should determine by direct observations whether proper caution signs are being used at access points to areas containing radioactive materials and radiation areas. During the conduct of the inspection the inspector should observe labeling on packages or other containers to determine that proper information (e.g., isotope, quantity, and date of measurement) is recorded.

During tours of the licensee's facilities, the inspector should verify that areas with radiation hazards have been conspicuously posted, as required by 10 CFR 20.1902. The inspector should determine that areas occupied by radiation workers for long periods of time and common-use areas have been controlled in accordance with licensee procedures and be consistent with the licensee's ALARA program.

During tours of the licensee's facilities, the inspector should observe locations where notices to workers are posted. The inspector should verify that applicable documents, notices, or forms are posted in a sufficient number of places to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the postings would apply in accordance with 10 CFR 19.11, 20.1902, and 21.6.

J. Inventories. Through discussions with cognizant licensee representatives, direct observations made during tours of the licensee's facility, and if necessary, a review of selected records, the inspector should verify that the licensee is conducting a semi-annual inventory of all sealed sources in accordance with 10 CFR 35.67(g). From those discussions, observations and reviews, if necessary, the inspector

should physically examine the inventory of radioactive material on hand or examine records of receipt and transfer to determine that the quantities and forms are as authorized in the license.

- K. Waste Storage and Disposal. The inspector should note that generally, radionuclides used in nuclear medicine facilities have half-lives of 120 days or less and can be decayed in storage until surveys are indistinguishable from background, then be disposed of as non-radioactive waste.

Through discussions with cognizant licensee representatives, direct observations made during tours of the licensee's facility, and if necessary, a review of selected records, the inspector should verify the following areas, when appropriate:

1. Waste disposed in accordance with 10 CFR 35.92;
2. Waste compacted in accordance with license conditions;
3. Waste storage containers properly labeled and area properly posted in accordance with 10 CFR 20.1902 and 20.1904; and
4. Waste was returned from a landfill due to radioactive contamination.

For further inspection guidance, the inspector should refer to IP 84850, "Radioactive Waste Management-Inspection of Waste Generator Requirements of 10 CFR Part 20 and 10 CFR Part 61"; and Information Notice (IN) 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR Part 20."

5. Effluents. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify that releases into a public sanitary sewerage system and septic tanks, if any, are consistent with the form and quantity restrictions of NRC regulatory requirements. If the inspector determines that a review of selected records is necessary, the inspector should pay particular attention to the licensee's documentation for demonstrating that the material is readily soluble (or readily dispersible biological material) in water. If a review of selected records is necessary, the inspector should examine the waste release records generated since the last inspection, annual or semiannual reports, pertinent nonroutine event reports, and a random selection of liquid and airborne waste release records.

For liquid wastes, the inspector should determine through further discussions, observations and reviews, if necessary, if the licensee has identified all sources of liquid waste; evaluated treatment methods to minimize concentrations (such as the use of retention tanks); and complies with the regulatory requirements for disposal into sanitary sewerage.

Through further discussions, direct observations made during tours of the licensee's facility, and reviews, if necessary, the inspector should verify that waste-handling equipment, monitoring equipment, and/or administrative controls are adequate to maintain radioactive effluents within NRC regulatory requirements and are ALARA (This should include xenon or other gas waste, also).

The inspector should review the licensee's ALARA goals, and determine if they are sufficiently challenging yet realistic. Through discussions with cognizant licensee representatives and direct observations of licensed activities, the inspector should determine if the licensee understands and implements these goals. From those discussions, observations and if necessary, a review of selected records, the inspector should determine if the licensee has calculated annual doses resulting

from air effluents and if the doses: 1) are within the licensee's ALARA goals (as described in its radiation protection program); 2) exceed the licensee's ALARA goals; or 3) are uncertain because there is insufficient information or basis for determination. Through further discussions and reviews, if necessary, the inspector should determine if the licensee's history demonstrates meeting ALARA goals, and its corrective actions when the goals were not met.

For further inspection guidance, the inspector should refer to IP 87102, "Maintaining Effluents from Materials Facilities As Low As Is Reasonably Achievable (ALARA).".

03.05 Shielding of Licensed Material.

Leak Tests. During the conduct of the inspection, the inspector should verify that leak tests of sealed or contained sources are performed at the required frequency found in 10 CFR 35.67(b) or license conditions. Through discussions with cognizant licensee representatives, direct observations, and if necessary, a review of selected records, the inspector should verify that the leak test is analyzed in accordance with 10 CFR 35.67(c). If records of leak test results show removable contamination in excess of the regulatory requirements of 0.005 microcuries (185 becquerels) or approved level included in a license condition, the inspector should verify that the licensee made the appropriate notifications per 10 CFR 35.67 (e) and removed the source from service.

03.06 Comprehensive Safety Measures.

During tours of the licensee's facilities, the inspector should be aware of potential industrial safety hazards for referral to the U. S. Department of Labor's Occupational Safety and Health Administration.

During tours of the facility and discussions with cognizant licensee representatives, the inspector should verify that the licensee's radioactive waste and licensed material are protected from fire and the elements, the integrity of packages containing licensed material is adequately maintained, areas used to store licensed material are properly ventilated, and adequate controls are in effect to minimize the risk from other hazardous materials.

03.07 Radiation Dosimetry Program.

The inspector can find specific inspection guidance for this area in IP 83822, "Radiation Protection."

1. Radiation Protection Program. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify that the licensee has developed, implemented and maintained an adequate radiation protection program commensurate with the licensee's activities, that the program includes ALARA provisions, and that the program is being reviewed by the licensee at least annually, both for content and implementation in accordance with 10 CFR 20.1101.
2. Occupational Radiation Exposure. From a review of selected occupational radiation dosimetry reports and discussions with cognizant licensee representatives, the inspector should determine that occupational radiation exposures received by workers are within NRC regulatory limits (e.g., 10 CFR 20.1201, 1202, 1207, and 1208). If from those reviews and discussions the inspector determines that a worker had exceeded an NRC regulatory limit, the inspector should immediately contact NRC regional management to discuss the matter and determine what steps need to be taken in following up on this matter.

10 CFR 19.13(b) requires that each licensee shall advise each worker annually of the worker's dose, as shown in dose records maintained by the licensee. Through discussions with cognizant licensee staff and management, the inspector should verify that the licensee has advised workers of their doses annually. The licensee must advise all workers for whom monitoring is required. The licensee must advise these workers of doses from routine operations, and doses received during planned special exposures, accidents, and emergencies. If the inspector cannot conclude from those discussions that workers had been advised of their occupational dose annually, then a records review may be more appropriate to confirm that the licensee had conducted this required task. The report to the individual must be in writing and must contain all the information required in 10 CFR 19.13(a).

3. Personnel Dosimeters. Through direct observations made during the onsite inspection, the inspector should independently verify that appropriate personal dosimetry devices are worn by appropriate licensee personnel. The inspector should verify that dosimetry devices appropriate to the type, energy or emitted radiation, and the anticipated radiation fields have been issued to facility personnel. In addition, the inspector should verify that dosimeters are processed by a National Voluntary Laboratory Accreditation Program approved and accredited processor.

Through discussions with cognizant licensee representatives and a review of selected records, the inspector should evaluate the adequacy of the licensee's methods used to assess the SDE to the portion of the skin of the extremity expected to have received the highest dose. The inspector should give particular attention to the distance between the location that is likely to have received the highest dose when sources are manipulated manually (even when shields are used) and where the extremity monitor is worn.

4. Internal Dosimetry. Through interviews with cognizant licensee representatives, and records review, if appropriate, verify that measurements for internal deposition of licensed materials are performed and evaluated in accordance with 10 CFR 20.1501.

03.08 Radiation Instrumentation and Surveys.

A. Equipment and Instrumentation

1. During the conduct of the inspection, the inspector should verify through discussions with cognizant licensee representatives, direct observations of licensed activities, and if necessary, a review of selected records, that equipment and instrumentation used to conduct licensed activities are appropriate to the scope of the licensed program, operable, calibrated, and adequately maintained in accordance with NRC regulatory requirements and the manufacturer's recommendations. The inspector should verify that:
 - a. the radiation survey instruments have been calibrated in accordance with 10 CFR 35.61;
 - b. the instruments used to measure the activity of unsealed byproduct material meet the requirements of 10 CFR 35.60; and
 - c. licensees that use molybdenum-99/technetium-99m generators measure and record the molybdenum-99 concentration after the first eluate, in accordance with 10 CFR 35.204, to ensure that humans are not administered a pharmaceutical containing more than 0.15 microcuries of molybdenum-99 per millicurie of technetium-99m.

The inspector should independently verify through direct observations that survey instruments have been calibrated at the required frequency in accordance with 10 CFR 35.61. The inspector should have cognizant licensee staff demonstrate how the instrument works and performs. The inspector should ask the individuals what actions are taken when radiation detection equipment is non-functional. During the inspection, the inspector should independently verify that for those survey and monitoring instruments available for use have current calibrations appropriate to the types and energies of radiation to be detected. For those licensee's that calibrate their own instruments, the inspector should have cognizant licensee staff perform or demonstrate how those activities are conducted in order to demonstrate the technical adequacy of the licensee's calibration procedures.

2. Through discussions with cognizant licensee representatives, the inspectors should independently verify that the licensee has procedures for identifying and reporting defects in accordance with Part 21. The complexity of the procedures will vary dependent upon the scope of the licensee's program.

- A. Area Radiation and Removable Contamination Surveys. During tours of the licensee's facility, the inspector should verify by direct observations and independent measurements, that area radiation levels are within NRC regulatory limits, and that those areas are properly posted. The inspector should have the licensee spot-check area radiation levels in selected areas using the licensee's own instrumentation. However, the inspector must use NRC radiation survey instruments for independent verification of the licensee's measurements. (The inspector's instruments shall be calibrated and source-checked before he/she leaves the NRC regional office.) The inspector should conduct such surveys as further discussed in Section 0312.

If practical, the inspector should observe licensee staff conduct area radiation and removable contamination surveys, to determine the adequacy of such surveys. The inspector should verify the types of instruments used, and whether they are designed and calibrated for the type of radiation being measured.

03.09 Radiation Safety Training and Practices.

- A. General Training. During the onsite inspection, the inspector should discuss with cognizant licensee staff how, and by whom, training is conducted and the content of the training provided to workers.

Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify, pursuant to 10 CFR 19.12, that instructions have been given to individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 1 milliSievert (100 mrem). The inspector should note that it is the licensee's management's responsibility to inform the workers of precautions to take when entering a restricted area, kinds and uses of radioactive materials in that area, exposure levels, and the types of protective equipment to be used. The workers should also be informed of the pertinent provisions of NRC regulations and the license, and the requirement to notify management of conditions observed that may, if not corrected, result in a violation of NRC requirements. Also, the inspector should verify that authorized users and workers understand the mechanism for raising safety concerns.

Of the training program elements, training given to authorized users and nuclear pharmacists, and those individuals under the supervision of authorized users and nuclear pharmacists, is of primary importance. The inspector should interview one

or more users of radioactive materials to independently verify that they have received the required training. The inspector should note that the training should be (and in most cases is required to be) provided to workers before the individual's performance of licensed activities.

If necessary, the inspector may need to review selected records of personnel training to the extent that the inspector is satisfied that the training program is being implemented as required.

During the inspection, the inspector should observe related activities and discuss the radiation safety training received by selected individuals to ensure that appropriate training was actually received by these individuals. From those observations and discussions, the inspector should verify that authorized users, authorized nuclear pharmacists and supervised individuals understand the radiation protection requirements associated with their assigned activities. The licensee's radiation safety training may include, but is not limited to, demonstrations by cognizant facility personnel, formal lectures, testing, films, "dry runs" for more complex or hazardous operations, and for authorized nuclear pharmacists instruction in the preparation of radioactive drugs.

B. Operating and Emergency Procedures.

Through discussions with cognizant licensee representatives, direct observations of licensed activities, and if necessary, a review of selected records, the inspector should verify that licensee staff are knowledgeable in conducting licensed activities in accordance with the licensee's operating procedures.

Some licensees may have agreements with other agencies (e.g., fire, law enforcement, and medical organizations) regarding response to emergencies. The inspector should discuss with cognizant licensee representatives what has been done to ensure that agencies (involved in such agreements) understand their roles in emergency responses.

C. Safety Instruction for Personnel Caring for Non-Releasable Patients. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should verify that the licensee provides radiation safety instruction for all personnel caring for patients who cannot be released under 10 CFR 35.75, in accordance with 10 CFR 35.310. The inspector should note that radiation safety instruction must be conducted initially and at least annually and be commensurate with the duties of the personnel.

D. Specialized Training. The inspector should note that specialized instruction required in 10 CFR 35.27 was provided to supervised users using material for medical uses or preparing byproduct material for medical use. The inspector should note that authorized users and research laboratory personnel should receive periodic radiation safety training commensurate with their use of licensed materials. For example, these individuals should know how and when to use radiation survey instrumentation, fume hoods, and protective gear. They should know procedures concerning waste disposal, bioassays, surveys, inventories, etc. Also, if the licensee uses licensed material for therapeutic purposes, training specific to the types of therapy performed should be provided to the nursing staff and others caring for these patients. This training should include personnel who do not directly deal with patients, such as housekeeping, maintenance, security, etc. The training should also include such topics as contamination control, ALARA, emergency procedures, and sealed source identification. The inspector should determine that personnel are appropriately trained through interviews, demonstration, and direct observation of licensed activities.

- E. Protective Clothing. Through direct observations of licensed activities and discussions with cognizant licensee representatives, the inspector should verify that radiation workers are provided with, and wear, the appropriate protective clothing commensurate with activities being performed. The observation of the protective clothing that research lab personnel or other applicable staff wear during their work activities should provide the inspector with an acceptable means of reviewing this requirement. If the inspector identifies a concern with this practice, the inspector should discuss this practice with appropriate licensee representatives to ensure that licensee staff are following licensee procedures for wearing adequate protective clothing.

03.10 Management Oversight.

The inspector should interview cognizant licensee representatives to gain information concerning organization, scope, and management oversight of the radiation safety program.

- A. Organization. During the conduct of the inspection, the inspector should interview cognizant licensee representatives to discuss the current organization of the licensee's program. The licensee's organizational structure will usually be found in the license application and may involve one or more individuals. The inspector should review with cognizant licensee representatives the licensee's organization with respect to changes that have occurred in personnel, functions, responsibilities, and authorities since the previous inspection. Through discussions with cognizant licensee representatives, the inspector should determine the reporting structure between executive management, the RSO, and the Chairperson of the RSC, and other members of the RSC. Through discussions with cognizant licensee staff, the inspector should determine whether the RSO has sufficient access to licensee management. Through further discussions with cognizant licensee representatives, the inspector should determine if changes in ownership or staffing have occurred. If the owner or individuals named in the license have changed, the inspector should determine whether the licensee has submitted appropriate notification to NRC. This information must be provided whenever changes in ownership or personnel named in the license are made. Through discussions with cognizant licensee management the inspector should determine if changes have occurred, or are anticipated, and ask personnel to confirm (to the inspector's satisfaction) that no changes have taken place. If there have been no changes in the organization since the previous inspection, there is no need to pursue this element in further detail. If there have been changes in ownership, the inspector should discuss this matter with appropriate licensee representatives and NRC regional staff (e.g., license reviewers) to ensure that proper actions will be taken in response to the changes in ownership.

Through discussions with cognizant licensee representatives, the inspector should review any organizational change in the RSO position, authorities, responsibilities, and reporting chains. The inspector should be sensitive to changes that reduce the ability of the RSO to resolve concerns or issues related to the safe conduct of the radiation protection program. The inspector should discuss with cognizant licensee management representatives and the RSO about the RSO's authority and about any changes that may impact upon the RSO's duties, responsibilities, or effectiveness.

- B. Scope of Program. Through discussions with cognizant licensee staff and direct observations of licensed activities, the inspector can obtain useful information about the types and quantities of material, frequency of use, incidents, etc. From those discussions and direct observations made during tours of the licensee's facilities, the inspector will be able to discern the actual size and scope of the licensee's program,

and to determine if significant changes have occurred since the previous inspection. Through further discussions inspector should determine if multiple places of use are listed on the license. In cases where there are multiple sites/satellite facilities, the inspector should determine if inspections should be performed at all sites. This decision should be based on MC 2800, "Materials Inspection Program," and regional policy for performing inspections at satellite facilities. From those observations and discussions, the inspector should verify that the locations of use are as authorized in the license. If the inspector determines that there are locations of use not authorized under the license, the inspector should discuss this matter with appropriate licensee representatives to ensure that the license is amended to allow the unauthorized location of use in accordance with 10 CFR 35.13 and/or 35.14. Furthermore, the inspector should determine if licensed activities conducted at such locations were conducted in accordance with NRC regulatory requirements and the licensee's license.

In reviewing the scope of the licensee's program in this area, the inspector should discuss information that includes the numbers of laboratories, permit holders, lab personnel, and locations of use; human research and medical use activities; mobile nuclear medicine services; distribution of pharmaceuticals under 10 CFR Part 35 license; and principal types and quantities of licensed materials used.

- C. Radiation Program Administration. In the course of interviewing cognizant licensee personnel, the inspector should determine if management oversight is sufficient to provide the licensee's staff with adequate resources and authority to administer the licensed program. In the review to verify implementation of the radiation safety program, the inspector should pay particular attention to the scope of the program, frequency of licensee audits, and the use of qualified auditors. If necessary, the inspector should review selected procedures for recording and reporting deficiencies to management; and methods and completion of follow-up actions by management.
1. RSO - The RSO is the individual, appointed by licensee management and identified on the license, who is responsible for implementing the radiation safety program. The inspector should independently verify through discussion and direct observations of licensed activities that this individual is knowledgeable about the program, and ensures that activities are being performed in accordance with approved procedures and the regulations. The inspector should verify that, when deficiencies are identified, the RSO has sufficient authority, without prior approval of the RSC, if applicable, to implement corrective actions, including termination of operations that pose a threat to health and safety.
 2. RSC - Through discussions with cognizant licensee representatives, direct observations of licensed activities, and if necessary, a review of selected records, the inspector should note if the licensee is required to maintain an RSC in accordance with 10 CFR 35.24(f). If applicable, through discussions with cognizant Radiation Safety Committee (RSC) representatives, the inspector should independently verify that topics of discussion during RSC meetings included ALARA reviews, incidents, generic communications, authorized users and uses, safety evaluations, audits, and medical events, as defined in 10 CFR 35.2, etc. From those discussions, the inspector should verify that the committee is made up of representatives from each type of program area, the RSO, a representative of the nursing service, and a representative from management. If time permits, the inspector should review meeting minutes (and interview selected committee members when practical) to determine the committee's effectiveness.

From those discussions, the inspector should determine if the RSC has been aggressive in seeking out areas needing improvement, rather than just responding to events and information from outside sources. The inspector should also determine whether the RSC has recommended any specific actions and assess the implementation of those recommendations. The inspector's review should be of sufficient depth and detail to provide an overall assessment of the committee's ability to identify, assess, and resolve issues. Also, the inspector should determine the effectiveness of the RSC to communicate the results of audits and trending analyses to appropriate personnel performing licensed activities.

Broad-scope medical programs may be authorized to conduct research involving the use of radioactive drugs or radiation-emitting devices in humans. Such research may require U.S. Food and Drug Administration (FDA) approval. In addition, approval to conduct research studies also requires input from an IRB, an RDRC, or other appropriate committee(s), including the RSC. The inspector should confirm that the licensee has received FDA approval, if required, and that studies involving the use of radioactivity in humans have been reviewed by the appropriate committee(s). The inspector should review the interaction between the RSC and the IRB and/or RDRC to assure compliance with the requirements in 10 CFR 35.6 as further discussed below in Section 3.10.K.

3. Audits - The frequency and scope of audits of the licensed program will vary. However, the inspector should note that at a minimum, medical licensees are required by 10 CFR 20.1101(c) to review the radiation safety program content and implementation at least annually. The results of audits should be documented. If time permits, the inspector should examine these records with particular attention to deficiencies identified by the auditors, and note any corrective actions taken as a result of deficiencies found. If no corrective actions were taken, the inspector through discussions with cognizant licensee representatives should determine why the licensee disregarded deficiencies identified during audits, and whether the lack of corrective actions caused the licensee to be in non-compliance with regulatory requirements.

- D. Authorized Individuals. Authorized individuals (physicians, nuclear pharmacists, and medical physicists) are appointed by the licensee. The inspector should independently verify that the authorized individual meets the training and experience criteria in Part 35, are trained in accordance with the approved criteria, and have knowledge commensurate with operational duties.

The inspector should note that the regulations in 10 CFR 35.11(b) allow an individual to receive, possess, use, or transfer byproduct material for medical use "under the supervision of" the authorized user, unless prohibited by license condition. Also, these regulations do not specifically require that the authorized user be present at all times during the use of such materials. The authorized user/supervisor is responsible for assuring that personnel under his/her supervision have been properly trained and instructed, pursuant to 10 CFR 35.27(a), and is responsible for the supervision of operations involving the use of radioactive materials whether he/she is present or absent.

Authorized users of licensed material for non-human use are generally designated by the RSC. The inspector should review the process of approving users through interviews with users, RSC members, and the RSO. The procedure for designating users can be found in the license documents. Verify that the authorized user received training in accordance with approved criteria and/or Part 35, and has knowledge commensurate with operational duties.

- E. Authorized Uses. Through discussions with cognizant licensee staff and direct observations made during tours of the licensee's facilities, the inspector should independently verify that the licensee's use of byproduct material (e.g., cell labeling, iodinations, animal research) is limited to that which is authorized in the license.
- F. Financial Assurance and Decommissioning. The decommissioning recordkeeping requirements are applicable to all materials licensees, including licensees with only sealed sources, and are specified in 10 CFR 30.35(g). These records should contain, among other information: 1) records of unusual occurrences involving the spread of contamination in and around the facility, equipment, or site; 2) as-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and locations of possible inaccessible contamination; and 3) records of the cost estimate performed for a decommissioning funding plan or the amount certified for decommissioning. This list is not all-inclusive of the information and requirements given in 10 CFR 30.35(g). The inspector should ensure that the licensee has such decommissioning records, that the records are complete, that they are updated as required, and that the decommissioning records are assembled or referenced in an identified location.

Some licensees may release rooms within a building for unrestricted use, without a license amendment. The release of these areas may fall outside of the reporting requirements in the Decommissioning Timeliness Rule if the licensee continues to conduct other activities in the same building. During the onsite inspection, the inspector should identify the rooms that have been released since the last inspection and perform confirmatory measurements to verify that radiation and contamination levels are below release limits. Licensee survey records and other documentation should be reviewed to verify that the basis for releasing each room is adequately documented in the licensee's decommissioning records. If during the confirmatory survey, the inspector identifies levels above release limits, the inspector should inform appropriate licensee representatives as soon as practicable to review the matter, determine what appropriate actions need to be taken to address the matter, determine if members of the public have been received radiation exposures that exceeded NRC regulatory limits, and assess those possible exposures. If the inspector determines that a member of the public may have received radiation exposures that exceeded NRC regulatory limits, the inspector should immediately contact NRC regional management for further guidance.

Licensees submit financial assurance instruments and/or decommissioning plans for a specific set of conditions. Occasionally, those conditions may change over time and the licensee may not notify NRC. The inspector should be aware of changes, in radiological conditions, while inspecting a licensee's facility, that would necessitate a change in the financial assurance instrument and/or decommissioning plan, especially where the radiological conditions deteriorate and the financial assurance instrument or decommissioning plan may no longer be sufficient. In preparation for the inspection, the inspector should determine the dates that the financial assurance instrument and decommissioning plan (if applicable) were submitted to NRC. During the inspection, through observations made during tours of the facilities, discussions with cognizant licensee personnel, and a review of selected records, the inspector should determine whether the radiological conditions at the licensee's facility have changed since the documents were submitted to NRC. If conditions have changed and the adequacy of the financial assurance instrument and/or decommissioning plan is in doubt, the inspector should contact regional management as soon as practicable from the licensee's site to discuss the situation.

Additionally, some licensees are required to maintain decommissioning cost estimates and funding methods on file. If the licensee uses a parent company guarantee or a self-guarantee as a funding method, the inspector should verify that

the licensee has a Certified Public Accountant certify each year that the licensee passes a financial test. The financial test ratios for parent company guarantees and self-guarantees are specified in Section II, Appendix A and Appendix C, respectively, to Part 30.

- G. Decommissioning Timeliness. Through discussions with cognizant licensee representatives and direct observations, the inspector should determine whether the license to conduct a principal activity has expired or been revoked. If the license remains in effect, the inspector should determine if the licensee has made a decision to cease principal activities at the site or in any separate building. Finally, the inspector should determine if there has been a 24-month duration in which no principal activities have been conducted in such areas. A principal activity is one which is essential to the purpose for which a license was issued or amended, and does not include storage incidental to decontamination or decommissioning. If the licensee meets any of the above conditions, the decommissioning timeliness requirements apply, and the inspector must complete in full Appendix B, "Decommissioning Timeliness."

The inspector should note that the requirements of 10 CFR 30.36, 40.42 and 70.38 do not apply to released rooms within a building where principal activities are still on-going in other parts of the same building. Once principal activities have ceased in the entire building, then the decommissioning timeliness requirements will take effect.

The inspector should note that the NRC has a stringent enforcement policy with respect to violations of the decommissioning timeliness requirements. Failure to comply with the Decommissioning Timeliness Rule (failure to notify NRC, failure to meet decommissioning standards, failure to complete decommissioning activities in accordance with regulation or license condition, or failure to meet required decommissioning schedules without adequate justification) may be classified as a Severity Level III violation and may result in consideration of monetary civil penalties or other enforcement actions, as appropriate.

Decommissioning timeliness issues can be complex. For situations where an inspector has questions about the licensee's status and whether the decommissioning timeliness standards apply, he/she should contact NRC regional management as soon as practicable for further guidance.

For planning and conducting inspections of licensees undergoing decommissioning, the inspector should refer to MC 2602, "Decommissioning Inspection Program for Fuel Cycle Facilities and Materials Licensees"; IP 87104, "Decommissioning Inspection Procedure for Materials Licensees"; and NUREG/BR-0241. "NMSS Handbook for Decommissioning Fuel Cycle and Materials Licensees."

- H. Generic Communications of Information. Through discussions with cognizant licensee management and the RSO as well as through direct observations made during tours of the licensee's facility, the inspector should verify that the licensee is receiving the applicable bulletins, information notices, NMSS Newsletter, etc., and that the information contained in these documents is disseminated to appropriate staff personnel. The inspector should also verify that the licensee has taken appropriate action in response to these NRC communications, when a response is required.
- I. Notifications and Reports. Through discussions with cognizant licensee representatives and if necessary, a review of selected records, the inspector should determine the licensee's compliance for notifications and reports to the Commission. The licensee may be required to make notifications following loss or theft of

material, overexposures, incidents, high radiation levels, safety-related equipment failure, medical events, dose to an embryo/fetus or a nursing child, etc.

From those discussions and reviews, the inspector should verify that notifications and/or reports were appropriately submitted to NRC and individuals, if applicable. If the inspector determines that the licensee failed to submit such notifications and/or reports, the inspector should bring this matter to the attention of appropriate licensee representatives as soon as practicable for followup and compliance to the appropriate NRC regulatory requirements.

- J. Special License Conditions. Some licenses will contain special license conditions that are unique to a particular practice or procedure, such as the use of equipment for nonmedical purposes. In these instances, through discussions with cognizant licensee representatives, the inspector should verify that the licensee understands the additional requirements, and maintains compliance with the special license conditions. The inspector should also note that some special license conditions may state an exemption to a particular NRC requirement.
- K. Research Involving Human Subjects. The inspector should verify through discussions with cognizant licensee representatives if research is conducted involving human research subjects. If applicable, the inspector must verify that this type of research satisfy the following conditions: 1) All research is conducted, supported, or regulated by another Federal Agency that has implemented "Federal Policy for Protection of Human Subjects" (10 CFR 35.6), or the licensee is authorized to conduct such research; 2) the licensee obtains informed consent from the subjects, as defined and described in the Federal Policy; and 3) the licensee obtains prior review and approval from an Institutional Review Board, as defined and described in the Federal Policy.

03.11 Other Medical Uses of Byproduct Material or Radiation from Byproduct Material. Due to the advancements of medical research and development, new emerging medical technologies are always on the forefront of providing optimal medical care to patients. Due to the increase in new emerging medical technologies, the regulations were revised to allow licensees the ability to use such new and emerging technologies in order to provide optimal patient care. In accordance with the regulations in 10 CFR 35.1000, the licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in subparts D through H of Part 35. In accordance with 10 CFR Part 33, the medical broad-scope licensee is required to perform a safety evaluation and have a record of the RSC's review and approval of the safety evaluation before implementing new uses. The safety evaluation should address the information in 10 CFR 35.12(b) through (d). In some cases the licensee may need an amendment for regulatory relief from specific requirements, and therefore will have specific conditions the NRC considers necessary for the medical use of the material. During discussions with cognizant licensee representatives and direct observations made during inspections, the inspector may encounter new emerging technologies being used. If an inspector encounters such a use, the inspector should inquire about the safety evaluation and if one has not been reviewed and approved by the RSC prior to use, the inspector should contact regional management as soon as practicable. If further verification of such use is needed, the region should contact NMSS for further guidance.

03.12 Independent and Confirmatory Measurements. During the conduct of the onsite inspection, the inspector should perform independent and confirmatory measurements in restricted, controlled, and unrestricted areas of the licensee's facility, when applicable. Independent measurements by the inspector should be performed on all inspections, unless exceptional circumstances make it impossible to perform the measurements (e.g., inspector's detection equipment malfunctions during an inspection trip; the licensee has never possessed license material since being issued a license). Measurements of dose rates at the boundaries of restricted areas should be performed by the inspector at the surfaces of

the most accessible planes. Examples of measurements that may be performed include area radiation surveys, wipe samples, leak tests, etc. These measurements should be taken in licensed material use areas, storage areas, etc. Confirmatory measurements are those whereby the inspector compares his/her measurements with those of the licensee's. Independent measurements are those performed by the inspector independently of the licensee's measurements. To perform the independent or confirmatory measurement, the inspector shall use NRC radiation detection instruments that are calibrated, at a minimum, on an annual basis.

03.13 Exit Meeting. When the inspection is over, there should be an exit meeting with the most senior licensee representative present at the facility. If a senior management representative is unavailable for the exit meeting, the inspector may hold a preliminary exit meeting with appropriate staff on site. However, there must be a formal exit meeting with a senior management representative (and the licensee's RSO, if not present at the preliminary exit meeting) as soon as practical after the inspection. This meeting can be held by a telephone conference call.

During the exit meeting, the licensee representatives should be told of the preliminary inspection findings, including any negative (PEFs), any apparent violations of regulatory requirements, safety-related concerns, or unresolved items identified during the inspection as well as the status of any previously identified violations. The inspector must ensure that the licensee immediately address any significant safety concerns.

If the inspector identifies safety concerns or violations of significant regulatory requirements that affect safe operation of a licensee facility, the licensee must initiate prompt corrective action. The inspector should not leave the site until the licensee fully understands the concern. If the inspector and the licensee disagree over how significantly the concern impacts the continued safe operation of the facility, the inspector should contact NRC regional management immediately to get further guidance on how to proceed.

Although deficiencies identified in some areas (e.g., workers' knowledge of the Part 20 requirements) are not always violations, the inspector should bring such deficiencies to the attention of licensee management at the exit meeting and also in the cover letter transmitting the inspection record or Notice of Violation, if applicable.

03.14 Post-Inspection Actions. Regional office policy will dictate with whom the inspector will review his or her inspection findings (e.g., the inspector's supervisor), following the guidance in MC 2800, "Materials Inspection Program." The inspector should discuss the findings in detail that is commensurate with the scope of the licensee's program. Violations, items of concern (e.g., negative PEFs), and unresolved items should be discussed in sufficient depth for management to make appropriate decisions regarding enforcement actions, referral to other State and Federal agencies, and decisions on the scheduling of future inspections of the licensee's facility.

The inspector should also discuss inspection findings with appropriate licensing staff. This information exchange can be particularly useful if the licensee is having its license renewed or has recently submitted a license amendment request. The inspector should inform appropriate licensing staff about how the licensee has addressed (or failed to address) special license amendments or recent licensing actions. Licensing information requested by the licensee should also be discussed with the licensing staff.

Inspectors should be aware that NRC has entered into several MOUs, with other Federal agencies, that outline agreements on items such as exchange of information and evidence in criminal proceedings. The inspector should ensure that the exchange of information relevant to inspection activities is made in accordance with the appropriate MOU.

The inspectors may report the results of inspections to the licensee either by issuing an NRC Form 591X or a regional office letter to the licensee, following the guidance in MC 2800. If applicable, the inspector must also ensure that the findings are appropriately documented in the NRC Form 591X-1, 2 and 3, in sufficient detail for the reader to determine what requirement was violated, how it was violated, who violated the requirement, and when it was violated. The NRC Form 591X-3 should be used to describe the scope of the program and what procedures or activities were observed and/or demonstrated by the licensee during the inspection, and any items of concern identified that were not cited as a violation of regulatory requirements.

If an NRC Form 591X-1, 2 and 3 cannot be completed due to the nature of the inspection findings, an inspection record (Appendix A) will need to be completed either by hand or electronically by the inspector.

For further inspection guidance, refer to MC 2800.

END

Appendices:

- A. "Medical Broad Scope Inspection Record"
- B. "Decommissioning Timeliness"

APPENDIX A
MEDICAL BROAD-SCOPE INSPECTION RECORD

Region _____

Inspection Record No. _____

License No. _____

-

Licensee (Name & Address):

Docket No. _____

-

Location(Authorized Site) Being Inspected:

Licensee Contact: _____ Telephone No. _____

-

Priority: _____ Program Code: _____ NMED/Event No(s): _____

Date of Last Inspection: _____

Date of This Inspection: _____

Type of Inspection: ☐ Announced ☐ Unannounced
 ☐ Routine ☐ Special
 ☐ Initial

Next Inspection Date _____ ☐ Normal ☐ Reduced

Justification for change in normal inspection frequency:

Summary of Findings and Actions:

- ☐ Violation(s), regional letter issued
- ☐ Follow-up on previous violations

Inspector(s) _____

Date _____

(Sign Name)

(Print Name)

Approved _____

Date _____

(Sign Name)

(Print Name)

PART I - INSPECTION, ENFORCEMENT, AND INCIDENT/MEDICAL EVENT HISTORY

1. INSPECTION AND ENFORCEMENT HISTORY:

(Unresolved issues; previous and repeat violations; Confirmatory Action Letters; and orders)

2. INCIDENT/MEDICAL EVENT HISTORY:

(List any incidents or medical events reported to NRC since the last inspection. Citing "None" indicates that regional event logs, event files, NMED and the licensing file have no evidence of any incidents or medical events since the last inspection.)

PART II - INSPECTION DOCUMENTATION

The inspection documentation part is to be used by the inspector to assist with the performance of the inspection. Note that all focus areas are to be addressed during each inspection; however, the inspector does not have to review each of the elements outlined in a focus area.

All areas covered during the inspection should be documented in sufficient detail to describe what activities and procedures were observed and/or demonstrated. In addition, the types of records that were reviewed and the time periods covered by those records should be noted. If the licensee demonstrated any practices at your request, describe those demonstrations. The observations and demonstrations you describe in this report, along with measurements and some records review, should substantiate your inspection findings. Attach copies of all licensee documents and records needed to support violations.

NOTE: Unless an inspector needs to intervene to prevent an unsafe situation, direct observation of work activities should be conducted such that the inspector's presence does not interfere with patient care or patient's privacy.

1. PERSONNEL CONTACTED:

[Identify licensee personnel contacted during the inspection (including those individuals contacted by telephone)]

Use the following identification symbols:

Individual(s) present at entrance meeting

* Individual(s) present at exit meeting

2. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

(Areas, both restricted and unrestricted, surveyed and measurements made; comparison of data with licensee's results and regulations; and instrument type and calibration date)

3. VIOLATIONS AND OTHER SAFETY ISSUES

(State requirement and how and when licensee violated the requirement. For non-cited violations, indicate why the violation was not cited. Describe the licensee's corrective actions, if provided during the exit meeting. Attach copies of all licensee documents needed to support violations.)

4. SPECIAL ISSUES

(Followup on Temporary Instructions that are currently in place. Describe other medical uses of byproduct material or radiation from byproduct material not previously identified)

5. PERFORMANCE EVALUATION FACTORS

- | | | |
|----|--|--|
| A. | Lack of senior management involvement with the radiation safety program and/or RSO oversight | <input type="checkbox"/> Y <input type="checkbox"/> N |
| B. | RSO too busy with other assignments | <input type="checkbox"/> Y <input type="checkbox"/> N |
| C. | Insufficient staffing | <input type="checkbox"/> Y <input type="checkbox"/> N |
| D. | RSC fails to meet or functions inadequately | <input type="checkbox"/> N/A <input type="checkbox"/> Y <input type="checkbox"/> N |
| E. | Inadequate consulting services or inadequate audits conducted | <input type="checkbox"/> N/A <input type="checkbox"/> Y <input type="checkbox"/> N |

Remarks [consider the above assessment and/or other pertinent Performance Evaluation Factors (PEFs) with regard to the licensee's oversight of the radiation safety program]:

PART III - FOCUS AREAS

1. SECURITY AND CONTROL OF LICENSED MATERIAL

(Adequate and authorized facilities; Adequate equipment and instrumentation; Receipt and transfer of licensed material; Transportation; Material security and control; Written directives; Medical events; Posting and labeling; Patient release; Waste storage and disposal; Effluents)

2. SHIELDING OF LICENSED MATERIAL.

(Leak tests)

3. COMPREHENSIVE SAFETY MEASURES.

(Potential industrial safety hazards; Adequate controls in place to minimize the risk from other hazardous materials)

4. RADIATION DOSIMETRY PROGRAM.

(Radiation protection program; Occupational radiation exposure; Personnel dosimeters, Internal dosimetry)

5. RADIATION INSTRUMENTATION AND SURVEYS.

(Instruments and equipment; Area radiation and removable contamination surveys)

6. RADIATION SAFETY TRAINING AND PRACTICES.

(General training; Operating and emergency procedures; Safety instruction for personnel caring for non-releasable patients; Specialized training; Protective clothing)

7. MANAGEMENT OVERSIGHT.

(Organization; Scope of program; Radiation program administration including RSO, audits, and RSC; Authorized users and uses; Financial assurance and decommissioning; Decommissioning timeliness; Generic communications of information; Notifications and reports; Special license conditions; Research involving human subjects)

PART IV - POST- INSPECTION ACTIVITIES

1. REGIONAL FOLLOW-UP (e.g., unresolved items):

2. DEBRIEF WITH REGIONAL STAFF:

(Post-inspection communication with supervisor, regional licensing staff, Agreement State Officer; and/or State Liaison Officer)

END

APPENDIX B
DECOMMISSIONING TIMELINESS

Licensee (location of authorized use): _____

—

Date (s) of Inspection: _____

1. COMPLIANCE WITH DECOMMISSIONING TIMELINESS RULE

A. License to conduct a *principal activity* has expired or been revoked () Y () N

B. Licensee has made a decision to permanently cease *principal activities* at the entire site, or any separate buildings, or any outdoor areas, including inactive burial grounds () Y () N

C. A 24-month duration has passed in which no *principal activities* have been conducted under the license at the site, or at any separate buildings, or any outdoor areas, including inactive burial grounds () Y () N

D. If "Yes" to either A or B or C above:

(1) Identify Site/Bldg/Area: _____

—

(2) Date(s) of occurrence of A, B, or C: _____

—

2. NOTIFICATION REQUIREMENTS

A. Licensee has provided written notification to U.S. NRC within 60 days of the occurrence of 1.A., 1.B., or 1.C. above () Y () N

If "Yes," date of notification: _____

B. If the licensee is requesting to delay initiation of the decommissioning process, the licensee has provided written notification to NRC within 30 days of occurrence of 1.A., 1.B., or 1.C. above () N/A () Y () N

If "Yes," date(s) of notification: _____

—

Basis for Findings:

3. DECOMMISSIONING PLAN/SCHEDULE REQUIREMENTS

- A. Licensee is required to submit a decommissioning plan per 10 CFR 30.36(g), 40.42(g), 70.38(g), or 10 CFR Part 72? () Y () N

If "No" to 3.A., answer the following items B. - F.:

- B. The decommissioning work scope is covered by current license conditions. () Y () N

- C. Decommissioning has been initiated within 60 days of notification to NRC, or NRC has granted a delay. () Y () N

- D. If licensee has initiated decommissioning, give date the decommissioning was initiated: _____

-

- E. If decommissioning has been completed, it was completed within 24 months of notification to NRC. () N/A () Y () N

- F. If decommissioning is still scheduled to be completed, it is on schedule to be completed within 24 months of notification to NRC. () N/A () Y () N

Basis for Findings:

If "Yes" to 3.A., answer the following items G. - J.:

- G. The decommissioning plan has been submitted to NRC within 12 months of notification. () Y () N

If "Yes," date of submittal: _____

—

If NRC approved, date of NRC approval: _____

-

- H. Has the licensee submitted an alternative schedule request?() Y () N

If "Yes," date of submittal: _____

—

- I. If decommissioning has been completed, it was completed within 24 months after approval of the decommissioning plan. () N/A () Y () N

- J. If decommissioning is still scheduled to be completed, it is on schedule to be completed within 24 months after approval of the decommissioning plan. () N/A () Y () N

Basis for Findings:

Violations identified, if any: